

Hellenic Accreditation System



Annex G1/17 to the Certificate No. **410-4**

SCOPE of ACCREDITATION

of the
Clinical Laboratory
of the
BIOHELLENIKA S.A.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Haematology Tests		
1. Peripheral blood, umbilical cord blood and nucleated cells from umbilical cord blood	1. Determination of the number of nucleated cells (granulocytes, lymphocytes, monocytes) and of the red blood cell count	Automated haematological analyzer CELLTAK MEK 6400K NIHON KOHDEN* BM-01 Ver. 13 th , 13/3/2019
2. Umbilical cord blood and nucleated cells from umbilical cord blood	1. Enumeration of viable CD45+dim/CD34+ haematopoietic progenitor cells	Flow cytometry according to ISHAGE guidelines and with STEM KIT (BECKMAN-COULTER) in Cytomics FC500, (Beckman-Coulter) BM-71 Ver. 3 rd 15/11/2018 and Facs Calibur (Becton Dickinson)* BM-59 Ver. 6 th 3/12/2019
3. Umbilical cord blood before processing	1. Identification of blood groups, anti-A, anti-B and anti-D antibodies	Visual inspection-flocculation test BM-57 Ver. 3 rd 22/9/2016
Microbiological Tests		
1. Umbilical cord blood	1. Test for bacterial infection (aerobic / anaerobic / yeasts)	Fluorescent medium, closed method (BACTEC/ BECTON DICKINSON)* BM-02 Ver. 7 th 12/6/2015
2. Umbilical cord blood plasma (CPD) and peripheral blood plasma (EDTA)	1. Detection of non-specific antibodies against <i>Treponema pallidum</i> – with the use of rapid plasma reagin	Visual inspection-flocculation test /RPR Carbon Test* BM-58 Ver. 3 rd 21/12/2011

